IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., BIOVAIL LABORATORIES INTERNATIONAL SRL, and ORTHO-MCNEIL, INC., Plaintiffs/Counterclaim Defendants, v. PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC., Defendants/Counterclaim Plaintiffs.	C.A. No. 07-255 (JJF) (CONSOLIDATED)

PURDUE'S AND NAPP'S RESPONSE TO DEFENDANTS' SUPPLEMENTAL BRIEF IN SUPPORT OF MOTION TO COMPEL PRODUCTION OF CERTAIN DISCOVERY AND AMEND SCHEDULING ORDER

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com

Attorneys for Plaintiffs
Purdue Pharma Products L.P.
and Napp Pharmaceutical Group Ltd.

Of Counsel:

Robert J. Goldman
Sasha G. Rao
ROPES & GRAY LLP
525 University Avenue
Suite 300
Palo Alto, CA 94301
(650) 617-4000

Sona De
Richard A. Inz
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, NY 10036
(212) 596-9000

Dated: July 16, 2008

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

RULES

I. PAR'S SUPPLEMENTAL BRIEF WAS PROCEDURALLY IMPROPER

On July 9, 2008, the Court informed the parties that defendant Par's Motion to Compel Production of Certain Discovery and Amend Scheduling Order ("Motion") (D.I. 152) would be decided on the papers. Without seeking leave of Court as required by L.R. 7.1.2(b), Par then filed a Supplemental Brief in support of its Motion. (D.I. 190). If the Court is going to consider Par's additional filing, plaintiffs Purdue Pharma Products L.P. ("Purdue") and Napp Pharmaceutical Group Ltd. ("Napp") respectfully request that the Court consider this brief response as well.

II. ARGUMENT

A. Par's Contentions As To The Scope Of "Subject Matter" Waiver Relating To The "Merck Reference" Are Unsound

The following facts are not in dispute. During the prosecution of a European counterpart to the patents at issue in this action, and in subsequent opposition and litigation involving that European patent, evidence describing certain experiments relating to the prior art "Merck reference" was submitted both by Napp and its adversaries. During the prosecution of the U.S. patents in suit, all of this evidence was provided to the Patent and Trademark Office ("PTO").

In discovery, Napp has produced documents underlying the evidence submitted by Napp in these European proceedings, including raw data for those tests and laboratory notebooks of the scientists and technicians who performed them. (Opp. 10).[1] Napp has also produced internal memoranda, emails, and file notes discussing these tests, including

[1] "Opp." refers to Purdue's and Napp's Corrected Opposition to Defendants Motion to Compel Production of Certain Discovery and Amend Scheduling Order (D.I. 187). "De Decl." refers to Corrected Declaration of Sona De (D.I. 188).

communications between Napp personnel and Napp's in-house patent counsel. Napp has produced in discovery test results both favorable and unfavorable to Napp, reflecting the evidence that was submitted in the European proceedings and also submitted to the U.S. PTO. Finally, Napp has produced communications with U.S. patent counsel relating to the evidence submitted in the European proceedings. Napp and its counsel have been deposed about these materials.

Napp has always maintained that, to the extent that the submission of evidence in European proceedings created a "subject matter waiver," the waiver extended to the work relating to Napp's testing based on the Merck reference. However, during discovery earlier in this case, Napp objected to reviewing the files of its foreign prosecution counsel and its litigation counsel relating to these matters on the grounds of undue burden as well as privilege and work product. (D.I. 85). Par moved to compel to overrule these objections and the Court denied Par's motion. (D.I. 126).

In its supplemental brief, Par contends that it is interested in five specific reports from the internal Napp "LIMS" electronic database that were identified in a Napp lab notebook. This is contradicted by the excerpt from Leslie deposition quoted in Par's brief. At the deposition, Par argued that there has been a "subject matter waiver" that would extend so far as to invade the confidential communications between Mr. Leslie and Napp's U.S. litigation counsel in preparation for Mr. Leslie's deposition. (Par Supp. Br., Ex. B, Leslie Tr. 17-18). Correspondence from Par's counsel reiterated this position. (Ex. A, p. 2, last paragraph).

Par's newly-minted argument for such a broad waiver is unsound. As a general matter of law, the scope of waiver, if any, is tested by a rule of reason, narrowly tailored to meet considerations of fairness, while still protecting the important attorney-client privilege and work

product immunity. *Hercules Incorporated v. Exxon Corp.*, 434 F. Supp. 136, 156 (D. Del. 1977).[2]

The law of this case is to the same effect. In its May 9, 2008 Order denying Par's Motion to Compel Foreign Documents (D.I. 126), the Court recognized that "[t]he foreign documents sought by defendants are potentially relevant, and some of the documents have been produced from the files of U.S. patent counsel without objection." Nevertheless, the Court denied Par's motion to compel further production, stating: "The issue that will resolve the motion is whether the documents produced by Plaintiff are sufficient given Defendants' asserted defenses and counterclaims."

Applying the Court's test, Napp's production to date has been entirely sufficient, because it allowed Par to test the bona fides of the evidence that was submitted in Europe and the U.S. PTO.

Par's supplemental brief contends that Par seeks production of five "LIMS" reports. The LIMS system is a Napp electronic database. The five reports were cited in a Napp laboratory notebook. The documents were *not* experiments submitted in European proceedings. If the issue were simply those five reports, Napp would produce them to resolve the dispute. Indeed, Napp offered to do so. (Ex. B).

But Par now seeks to use the five LIMS reports as a wedge to (1) circumvent the Court's May 9 Order and compel Napp to review the voluminous files of its foreign patent and

---

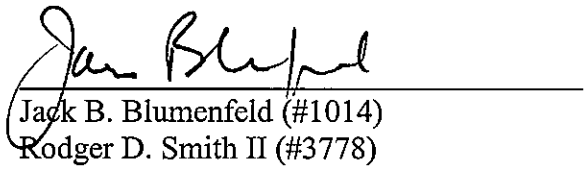
[2] Under Par's theory, once a party has waived privilege as to any subject by virtue of pre-suit conduct, the waiver would extend to subsequent communications with litigation counsel. That is not the law. *In re Seagate Technology*, 497 F.3d 1360, 1372-76 (Fed. Cir. 2007). Par's complaint that Napp blocked deposition testimony regarding Merck testing is thus misplaced. The question objected to related to deposition preparation, not testing of the Merck reference. Counsel for Napp offered to deal with the waiver disagreement on a question by question basis. (Par Br., Ex. B at 18:5-22). Counsel for Par then moved on to another topic. (*Id.*).

litigation counsel in search of additional documents; and (2) invade the attorney-client privilege and work product immunity far more broadly than circumstances warrant. This is unsound.

B. The Recall Of Additional Napp Documents Was Proper Pursuant To The Protective Order

Napp promptly and properly recalled the approximately 50 documents upon realizing that they were inadvertently produced. As set forth in Purdue and Napp's opposition brief, this was completely proper under the Protective Order.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com

Attorneys for Plaintiffs
Purdue Pharma Products L.P.
and Napp Pharmaceutical Group Ltd.

Of Counsel:

Robert J. Goldman
Sasha G. Rao
ROPES & GRAY LLP
525 University Avenue
Suite 300
Palo Alto, CA 94301
(650) 617-4000

Sona De
Richard A. Inz
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, NY 10036
(212) 596-9000

Dated: July 16, 2008

2413114

CERTIFICATE OF SERVICE

I hereby certify that on July 16, 2008, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Frederick L. Cottrell, III, Esquire
Steven J. Fineman, Esquire
Richards, Layton & Finger, P.A.

Richard D. Kirk, Esquire
The Bayard Firm

Mary W. Bourke, Esquire
Connolly Bove Lodge & Hutz LLP

I further certify that I caused to be served copies of the foregoing document on July 16, 2008, upon the following in the manner indicated:

Frederick L. Cottrell, III, Esquire
Steven J. Fineman, Esquire
Richards, Layton & Finger, P.A.
One Rodney Square
Wilmington, DE 19801

VIA ELECTRONIC MAIL AND HAND DELIVERY

Edgar H. Haug, Esquire
Robert E. Colletti, Esquire
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151

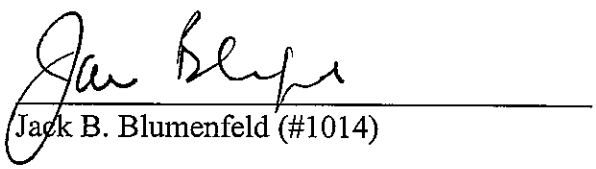
VIA ELECTRONIC MAIL AND FIRST CLASS MAIL

Richard D. Kirk, Esquire
The Bayard Firm
222 Delaware Avenue
Suite 900
Wilmington, DE 19801

VIA ELECTRONIC MAIL AND HAND DELIVERY

Mary W. Bourke, Esquire
Connolly Bove Lodge & Hutz LLP
The Nemours Building
1007 North Orange Street
Wilmington, DE 19801

VIA ELECTRONIC MAIL AND HAND DELIVERY



Jack B. Blumenfeld (#1014)

EXHIBIT A

FROMMER LAWRENCE & HAUG LLP

New York
745 Fifth Avenue
New York, NY 10151
Telephone: (212) 588-0800
Fax: (212) 588-0500

www.flhlaw.com

Washington, DC
Tokyo

Robert E. Colletti
rcolletti@flhlaw.com

July 14, 2008

VIA ELECTRONIC MAIL

Robert J. Goldman, Esq.
Ropes & Gray
525 University Avenue
Suite 300
Palo Alto, CA 94301-1917

Re: *Purdue et al. v. Par Pharmaceutical et al.*
FLH Reference No. 540572-521

Dear Bob,

This is a follow-up to our conversation this morning wherein you proposed a potential compromise to at least one portion of Par's Motion to Compel Certain Discovery. Based on our conversation I am not clear as to the exact terms of the compromise so to avoid any misunderstanding, I am reiterating the facts and the parties' positions before addressing a potential compromise.

In 1995 and 1997 Napp carried out experimentation following the teachings of EP 0 147 780 (the "Merck reference"). The results of some of those experiments were set forth in the July 26, 1995 and November 19, 1997 public declarations of Napp employee, Ms. Sandra Malkowska. Napp originally submitted those declarations during a European opposition proceeding and then subsequently filed them with the U.S. Patent Office in 1999 and 2000 to establish patentability over the Merck reference. As a result of Napp's public submissions regarding its experimentation following the teaching of the Merck reference (including the Malkowska declarations and Napp's unfavorable repeat experiments performed before third parties during the *Napp v. Asta* U.K. litigation), there has been a subject matter waiver. Napp cannot present experimentation following the teaching of the Merck reference that is favorable to its position of patentability to the U.S. Patent Office and withhold contradictory experimentation.

Napp has continually contested that there was been a subject matter waiver. Hence, Par moved to compel documentation that Napp was withholding as privileged. In its opposition brief, Napp ignored the merits of Par's argument regarding a waiver of privilege and contended that the waiver issue was moot. I do not understand how Napp can dodge the question regarding subject matter waiver in its brief and then contend the issue is moot. Napp's brief stated it had "produced all internal Napp documents requested by Par related to its experimentation based on the Merck reference, except for sixteen additional documents that are being produced today." Napp's statement does not tell Par or the Court whether Napp is contesting whether there

is a subject matter waiver. Moreover, Napp's statement was incorrect. As our July 9 letter explained, Napp carried out experimentation in 1998 following the teachings of the Merck reference, as evidenced in Napp's formulation notebook F644. Napp does not dispute that it is currently withholding as privileged the analytical data associated with this experimentation (although I am not certain these documents are listed on its privilege logs). Instead, Napp is now proposing a compromise.

This morning you asked whether Par was willing to drop its motion to compel regarding subject matter waiver if Napp agreed to produce the above-described analytical data and make a written representation that there was no other Napp experimentation relating to the Merck reference. Unfortunately, that is not an acceptable compromise because it does not address the subject matter waiver issue. Is Napp offering to produce the analytical documents we identified because it agrees there has been a subject matter waiver regarding experimentation that follows the teaching of the Merck reference?

Without an agreement that Napp has waived privilege regarding its experimentation following the teaching of the Merck reference, Napp could continue to assert privilege, withhold documents, and prevent testimony pertaining to its experimentation following the Merck reference. Hence, any compromise must address the subject matter waiver issue. Napp must produce not only the analytical documentation described above but its communications regarding that experimentation (including communications with counsel). We are of course amenable to working out language regarding the scope of the subject matter waiver.

Sincerely,

Robert E. Colletti

Robert E. Colletti

cc: Frederick L. Cottrell, Esq.

EXHIBIT B

ROPES & GRAY LLP
1211 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-8704
WWW.ROPESGRAY.COM

Robert J. Goldman
650-617-4035
650-566-4150 fax
robert.goldman@ropesgray.com

July 15, 2008

BY E-MAIL

Robert E. Colletti, Esq.
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151

Purdue, et al. v. Par

Dear Rob:

This is in response to your July 14 letter about our discussions relating to Par's motion to compel production of documents relating to the "Merck reference."

You contend that, because Napp submitted certain experiments relating to the Merck reference in foreign patent proceedings, both prosecution and litigation, there has been a "subject matter waiver." You ask at another point whether Napp "agrees that there has been a subject matter waiver regarding experimentation that follows the teaching of the Merck reference."

Your question highlights the problem that Napp has had in trying to address Par's requests for documents about the Merck reference. The issue is not whether there has been some waiver of work product and privilege flowing from the submission of those experiments. Napp has already produced the documents underlying the experiments that were submitted in Europe, as well as internal memoranda discussing these tests, including communications between the scientists who ran the tests and Napp's counsel. Par has examined several witnesses at deposition about these documents. Rather, the issue is what the reasonable scope of that waiver should be.

Par has always contended that the waiver should be broader than the experiments themselves, but its contentions have not been consistent. In your July 9 letter to me, I understood you to be narrowing Par's focus to the five specific reports from the internal Napp "LIMS" electronic database that were identified in a Napp lab notebook. However, at the Leslie deposition, your associate appeared to widen Par's contention again, when he argued that there had been a "subject matter waiver" that would extend so far as to invade the confidential communications

between Mr. Leslie and me at our meeting before his deposition. (Leslie Tr. 17-18). This latter contention is plainly unsound.

The Court's May 9, 2008 Order denying Par's Motion to Compel Foreign Documents (D.I. 126) also needs to be considered. The Court recognized there that "The foreign documents sought by defendants are potentially relevant, and some of the documents have been produced from the files of U.S. patent counsel without objection." Nevertheless, the Court denied Par's motion to compel further production, stating: "The issue that will resolve the motion is whether the documents produced by Plaintiff are sufficient given Defendants' asserted defenses and counterclaims."

Taking that as a test, Par's contention as set forth in your July 14 letter appears to be that some testing was done, and that Napp has withheld "contradictory experimentation." Napp disagrees with this contention because the documents already produced – and provided to the PTO during prosecution of the patents in suit – included all of the evidence concerning experiments that was submitted in the foreign litigations, including those experiments done on behalf of both Napp and its adversaries.

Nevertheless, your letter appears to point towards a compromise solution to the scope of waiver. It was for that reason that Napp offered to produce the five LIMS reports previously identified, and to search the LIMS system to see if any other tests were run on a controlled release tramadol product based on the "Merck reference" in any of the European proceedings. If such tests are found, then the parties would be free to argue whether or not they are contradictory to what was submitted to the United States PTO, which is the only relevant issue in this action.

Napp believes it very unlikely that the Court would order a waiver as broad as your colleague argued for at the Leslie deposition. And Napp recognizes that the Court might order a waiver broader than just the documents underlying the actual tests that were submitted in Europe. Napp proposed a middle ground designed to get Par the documents it claims to need, sooner rather than later, and to do so without burdening the Court on this issue.

The last paragraph of your letter, which demands that Napp also produce "its communications regarding that experimentation (including communications with counsel)" is not a compromise at all. To make that production, Napp would have to review the voluminous files that Par sought in its unsuccessful motion to compel, as well as re-review its withheld document log. This would take considerable time and add considerable expense to an already expensive action. The burden of undertaking these tasks outweighs Par's hope that something relevant will turn up in those files. Par tried this argument once before and the Court rejected it.

As long as Par's contentions about the scope of "subject matter waiver" remain overly broad, or ever-changing, we cannot resolve the matter, and we will wait for a ruling by the

Court before proceeding. If, however, Par accepts Napp's proposed compromise, we will be able to search the electronic LIMS database and, hopefully, complete production of any additional documents before opening expert reports are due on July 25th.

Sincerely,

Robert J. Goldman

RJG:alc

cc: Jack B. Blumenfeld, Esq.
Frederick L. Cottrell III Esq.